JUN 13 2012

## Section 5

## 510(k) Summary

| | | |
|---|---|---|
| **General Provisions** | Submitter Name:<br>Address:<br><br>Telephone Number:<br>Fax Number:<br>Contact Person:<br>Date of Preparation:<br>Registration Number: | Merit Medical Systems, Inc.<br>1600 West Merit Parkway<br>South Jordan, UT 84095<br>(801) 208-4196<br>(801) 253-6932<br>Michaela Rivkowich<br>April 5, 2012<br>1721504 |
| **Subject Device** | Trade Name:<br>Common/Usual Name:<br>Classification Name: | 6 French Concierge® Guiding Catheter<br>Guiding Catheter<br>Percutaneous Catheter |
| **Predicate Device** | Trade Name:<br>Common/Usual Name:<br>Classification Name:<br>Premarket Notification:<br>Manufacturer: | Concierge® Guiding Catheter<br>Guiding Catheter<br>Percutaneous Catheter<br>K043387<br>Merit Medical Systems, Inc. |
| **Classification** | Class II<br>21 CFR § 870.1250<br>Cardiovascular | |
| **Intended Use** | The Concierge Guiding Catheter is intended for the intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems. | |
| **Device Description** | The 6 French Concierge Guiding Catheter is a single lumen catheter that incorporates a nylon body reinforced with stainless steel wire braid, a PTFE lubricious inner lumen, and a soft radiopaque tip. It is available in 6F size and 100cm length and in a variety of shapes. | |

K121051
P. 2 of 3

| | |
|---|---|
| **Technological Characteristics** | The technological characteristics of the subject 6 French Concierge Guiding Catheter are substantially equivalent to those of the predicate device, the Concierge Guiding Catheter, 510(k) K043387. |
| **Safety & Performance Tests** | No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. Performance testing of the subject 6 French Concierge Guiding Catheter was conducted based on the risk analysis and based on the requirements of the following FDA guidance document and international standards:<br>• ISO 10555-1:1995, *Sterile, single-use intravascular catheters – Part 1: General requirements*<br>• ISO 10555-2:1996, *Sterile, single-use intravascular catheters – Part 2: Angiographic catheters*<br>• ANSI/AAMI/ISO 11135-1: 2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*<br>• ISO 10993-1: 2009, *Biological Evaluation of Medical Devices Part-1: Evaluation and Testing within a risk management process,* and the FDA Modified ISO 10993 Test Profile<br>• ASTM F756-08, *Standard Practice for Assessment of Hemolytic Properties of Materials*<br>• ISO 10993-3 :2003, *Biological Evaluation of Medical Devices Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity*<br>• ISO 10993-4:2002, *Biological evaluation of medical devices – Part 4: Selection of tests for interaction with blood*<br>• ISO 10993-5:2009, *Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity*<br>• ISO 10993-10:2010, *Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization*<br>• ISO 10993-11:2006, *Biological evaluation of medical devices – Part 11: Tests for systemic toxicity*<br>• ISO 2233:2000, *Packaging – complete, filled transport packages and unit loads – conditioning and testing*<br>• ASTM D4169-08, *Standard practice for performance testing of shipping containers and systems*<br><br>The following is a list of all significant testing that was successfully completed: |

| | |
|---|---|
| **Safety & Performance Tests cont.** | <u>Design Verification</u><br>Dimensions<br>Air Leak<br>Liquid Leak<br>Catheter Tip Support and Attachment<br>Tensile<br>Shaft Kink<br>Shaft Stiffness<br>Ink Adherence<br><br><u>Biocompatibility Tests</u><br>Cytotoxicity<br>Sensitization<br>Irritation<br>Accute Systemic Toxicity<br>Genotoxicity<br>Hemocompatibility<br>Physicochemical Tests |
| **Safety & Performance Tests cont.** | The results of the testing demonstrated that the subject 6 French Concierge Guiding Catheter met the pre-determined acceptance criteria applicable to the safety and efficacy of the device. |
| **Summary of Substantial Equivalence** | Based on the indications for use, design, and safety and performance testing, the subject 6 French Concierge Guiding Catheter meets the requirements that are considered essential for its intended use and is substantially equivalent to the predicate device, the Concierge Guiding Catheter, manufactured by Merit Medical Systems, Inc. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 13 2012

Merit Medical Systems, Inc.
c/o Ms. Michaela Rivkowich
Principal Regulatory Affairs Specialist
1600 West Merit Parkway
South Jordan, UT 84095

Re: K121051
Trade/Device Name: 6 French Concierge Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: May 10, 2012
Received: May 14, 2012

Dear Ms. Rivkowich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Section 4

## Indications for Use

510(k) Number (if known): K121051

Device Name: 6 French Concierge® Guiding Catheter

Indications for Use:
The Concierge® Guiding Catheter is intended for the intravascular introduction of interventional/diagnostic devices into the coronary or peripheral vascular systems.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

5[illegible](k) Number K121051